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**February 12, 2004**

**SEND TO:** Examiner Fenn C. Mathew  
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**FROM:** Joan T. Kluger  
**CLIENT #:** 3000111-0006  
**ATTY#:** 2700  
**RE:** Our Ref.: 1213-01

**NUMBER OF PAGES INCLUDING COVER PAGE: 12**

**COMMENTS:**

Draft amendment for discussion on February 17, 2004 at 11:00. Please do not enter into the record.

We look forward to meeting with you.

**IF THERE IS A PROBLEM, CALL: (215) 751-2357**

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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FEB 20 2004

Art Unit : 3764  
Examiner : Fenn C. Mathew  
Serial No. : 10/001,451  
Filed : October 23, 2001  
Inventors : Lisa A.G. Twardy  
: Will Pickering  
: Clay Burns  
Docket: 1213-01  
Title : CERVICAL BRACE

22469

Confirmation No.: 2404  
Dated: DRAFT

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**RESPONSE**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In response to the Official Action dated November 5, 2003, please amend the above-identified application without prejudice as follows:

**DRAFT****SUBMITTED FOR DISCUSSION PURPOSES ONLY****DO NOT ENTER INTO RECORD**

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In The Claims

Claims 1-10, 16, 19, 20, 25, 27-29 30, 33 and 34 are cancelled.

14. (Allowed) The brace of claim 32, wherein said latch and latch housing comprise an eccentric element that moves into and out of engagement with a locking mechanism, whereby the angle of the rear strut relative to the rear portion may be adjusted.
17. (Allowed) The brace of claim 32, further comprising a head strap extending from said occipital support.
18. (Allowed) The brace of claim 32, wherein said latch housing comprises one or more extensions and the vest comprises one or more locking slots, whereby said extensions and said locking slots engage said rear strut with said vest.
24. (Previously amended) A cervical brace comprising:  
a cervical collar having front and rear portions, wherein said rear portion comprises an occipital support;  
a vest comprising a front plate and a back plate, and means for attachment of said front plate to said cervical collar front portion, wherein said back plate is free from attachment to said cervical collar rear portion.
26. (Currently amended) The method of claim 49 further comprising:  
adjusting the vertical height of the chest plate said anterior plate assembly independently of said adjustment of the relative position of said chin strut and said chest plate.
31. (Currently amended) The cervical brace of claim 27.5 wherein said chin strut is adjustably attached to said chest plate anterior plate assembly.

32. (Allowed) A cervical brace comprising:

a cervical collar having front and rear portions, wherein said rear portion comprises an occipital support;

a vest comprising a front plate and a back plate;

a rear strut extending between said occipital support and said back plate;

a rear strut latch, whereby the relative position of said rear strut may be adjusted both angularly and vertically;

a latch and latch housing disposed on said rear portion; and

wherein said latch housing comprises one or more receiving elements that engage said latch to adjust the relative distance between said cervical collar and said vest.

35. (New) A cervical brace for attachment to a cervical collar comprising:

an anterior plate assembly having an upper front plate and a lower front plate wherein said upper front plate is adjustably attached to said lower front plate; and

a chin strut attached to said anterior plate assembly, wherein said chin strut has a detachable attachment point for attachment of said chin strut to a chin support of said cervical collar.

36. (New) The cervical brace of claim 35, further comprising a vest wherein said anterior plate assembly is a portion of said vest.

37. (New) The cervical brace of claim 36, wherein said vest further comprises a back plate.

38. (New) The cervical brace of claim 35, wherein said chin strut extends in a straight line from said anterior plate assembly to said chin support.

39. (New) The cervical collar of claim 31, wherein adjustability is provided by attachment of said chin support and said anterior plate assembly using hook-and-loop fasteners.

40. (New) The cervical brace of claim 35, further comprising:

a back plate;

an occipital support; and

a rear strut extending between said occipital support and said back plate.

41. (New) The cervical brace of claim 40 further including straps for securing said back plate to said anterior plate assembly.

42. (New) The cervical brace of claim 40 wherein said rear strut is adjustable and further comprises a strut lock.

43. (New) The cervical brace of claim 42 wherein said strut lock comprises an eccentric lever for locking one end of said rear strut to a bracket affixed to said back plate.

44. (New) A cervical brace for attachment to a cervical collar comprising:  
an anterior plate assembly adapted to be secured to the thorax of a wearer;  
a chin strut including means for attachment to said chest plate and means for attachment to a chin support of said cervical collar, said chin support to be disposed adjacent said wearer's chin;  
a back plate;  
an occipital support; and  
a rear strut extending between said occipital support and said back plate, wherein said rear strut is adjustable and includes a strut lock, and wherein said strut lock comprises an eccentric lever for locking one end of said rear strut to a bracket affixed to said back plate.

45. (New) The cervical brace of claim 44 wherein said back plate is attached to said anterior plate assembly.

46. (New) The cervical brace of claim 45 further comprising straps for securing said back plate to said anterior plate assembly.

47. (New) The cervical brace of claim 44 wherein said rear strut includes means for independently adjusting the height and angle of attachment of said rear strut to said back plate.

48. (New) A cervical brace for attachment to a cervical collar comprising:  
an anterior plate assembly adapted to be secured to the thorax of a wearer;  
a chin strut including means for attachment to said anterior plate assembly and means for attachment to a chin support of said cervical collar, said chin support to be disposed adjacent said wearer's chin;  
wherein said latch housing and said latch comprise corresponding serrated surfaces that move into and out of engagement upon rotation of said latch relative to said housing; and  
wherein said chin strut is detachably connected to said chin support of said cervical collar.

49. (New) A method of supporting one of the cervical spine or upper thoracic spine of a patient comprising:

attaching a cervical collar to the patient;  
attaching a chin strut from said cervical collar to a anterior plate assembly and adjusting the relative position of the head by selecting a relative position between said chin strut and said anterior plate assembly;  
attaching said anterior plate assembly to the patient's thorax;  
attaching an occipital support to the patient;  
attaching a rear strut to said occipital support;  
attaching a back plate to the patient;  
adjusting said rear strut; and  
locking, with an eccentric lever, said rear strut to said back plate.

50. (New) The method of claim 49 further comprising securing said back plate to said anterior assembly with straps.

51. (New) A method of bracing the cervical spine or thoracic spine of a patient comprising:

attaching a cervical collar to said patient wherein said cervical collar has a front portion and a rear portion with an occipital support;  
attaching a vest to said patient wherein said vest has a front plate and a back plate;  
attaching said front plate to said cervical collar front portion; and  
leaving said back plate free from attachment to said cervical collar rear portion.

attaching a chin strut from said cervical collar to a anterior plate assembly and  
adjusting the relative position of the head by selecting a relative position between said  
chin strut and said anterior plate assembly;  
attaching said anterior plate assembly to the patient's thorax.

Remarks

Claims 1-10, 14, 16-20 and 24-34 are pending. Claims 14, 17, 18 and 32 are allowed.

Claims 1-9, 19, 20, 24-31 and 34 are rejected. Claims 10 and 16 are objected to.

Claim Rejections under 35 U.S.C. §112

Claim 34 has been rejected under 35 U.S.C. §112 first paragraph. Applicants maintain that the chin strut extending non-vertically is disclosed in the specification. See for example part 102 in FIG 6A. Nonetheless, and unrelated to this rejection, claim 34 has been cancelled.

Claim Rejections under 35 U.S.C. §102

Claims 1-5, 7-9, 19-20, 24, 28-29 and 33 are rejected under 35 U.S.C. §102(e) as being anticipated by Garth. With the exception of claim 24, the aforementioned claims have either been cancelled or amended to depend on new claim 35. New claim 35 is not anticipated by Garth.

Claim 35 includes an anterior assembly having a lower plate adjustably attached to an upper plate (p.5, paragraph 22). Claim 35 also includes a chin strut having an attachment point for detachable attachment of the chin strut to a chin support of a cervical collar (p.6, paragraph 23). Garth does not disclose either of these claimed elements.

Very significantly, Garth does not disclose a support attached to a "chin" support. Garth's front strut attaches to points below any chin support (see FIG. 3, attachment 109 for support 120). Having the chin strut attached to a chin support is important because it prohibits or reduces flexing forward of the neck.

Garth clearly does not disclose a lower plate adjustably attached to an upper plate.

Garth's chin strut is not detachable from the collar. Garth discloses a strut attached to a collar with pivotal or hinged attachments 109 & 109A (col.3, lines 58-67). The pivotal attachments permit the strut mechanism to be rotated in relation to the neck collar (col. 3, line 66 - col. 4, line 1; and col.4, lines 26-34) for the purpose of access to the chest without removing the device entirely. These are the limitations disclosed in Garth with respect to the strut attachment to the collar. Garth does not disclose that the collar is detachable from the strut. Garth designates when his disclosed fasteners are detachable. For example, Garth discloses detachable fasteners to hold various portions of the collar to one another, not parts of the collar to the strut (col.3, lines 27-45). Applicants respectfully submit that the Examiner is reading more into Garth's disclosure than exists.

As Garth does not disclose these elements that are contained in Applicants' independent claim 35, it, and claims 36-43, which depend thereon, are not anticipated by Garth.

Claim 24 was also rejected as being anticipated by Garth. Claim 24 includes a back plate that is free from attachment to the cervical collar. This is a novel concept and is neither taught nor suggested by Garth. The Examiner states that Garth's back plate is "capable" of being free from attachment to the cervical collar, however, Garth does not disclose such an embodiment. To the contrary, Garth teaches only attaching a back plate to a collar (Fig. 2 and col. 5, lines 23-24). Nowhere is it indicated that Garth recognizes that it may be beneficial for the back plate to be free from attachment to the cervical collar. Applicants' invention of claim 24 acts to reduce compensatory motion, unlike Garth's over-constrained system. In an over-constrained system, as disclosed in Garth, unwanted motion is created to compensate for the inability to move in a manner to accommodate certain activities, such as transitioning from a sitting position to a

standing position, or a prone position to a sitting position. Further more, a patient using applicants' claimed invention may lay flat on his/her back with their head in a different position than it was when upright, which is the normal tendency. Garth's invention would require a patient to have the same relative position of the neck and back, whether prone, standing or sitting. As this is not natural, it can be very uncomfortable. Accordingly, as Garth does not disclose applicants' "free back", claim 24 is patentable over Garth.

New claim 25 is a method claim based on the apparatus claim 24 and can be performed utilizing the apparatus of claim 24. Accordingly, for the same~~4e~~ reasons as claim 24 is patentable over Garth, so is claim 51.

Withdrawal of the 35 U.S.C. §102 rejections are therefore, respectfully requested.

It is noted that Applicants have replaced the term "chest plate" with "anterior plate assembly" in the claims because the specification more clearly describes the term. It is also more in keeping with the language of the majority of the specification. The anterior plate assembly, preferably comprises two plates (p.5, paragraph 22), but the invention is not limited to such and encompasses one or more plates.

#### Claim Rejections under 35 U.S.C. §103

Claim 6 is rejected under 35 U.S.C. §103(a) as being unpatentable over Garth. This rejection is respectfully traversed. Unrelated to this rejection, claim 6 has been cancelled.

Claims 25-27, 30 and 31 are rejected under 35 U.S.C. §103(a) as being unpatentable over Garth in view of Mattingly. This rejection is respectfully traversed. Unrelated to this rejection, claims 25, 27 and 30 have been cancelled. Claim 31 is

dependent on claim 35, and therefore, for reasons stated above, is patentable over Garth. Claim 26 has been amended to depend on new claim 49. New claim 49 is a method claim that parallels allowed claim 32. The method described in claim 49 can be performed with the apparatus of claim 32 and also is not anticipated by Garth. Garth does not disclose attaching a chin strut from the cervical collar to an anterior assembly, and adjusting a rear strut and locking it, with an eccentric lever, to a back plate. Therefore, neither claim 49, nor claims 26 and 50, which depend thereon, are anticipated by Garth.

Mattingly does not overcome the shortcomings of Garth. First, Mattingly is not analogous art because Mattingly does not disclose a cervical collar or a device to be used with a cervical collar as is claimed by Applicants. Mattingly is a halo brace. Furthermore, there is no motivation to combine the teachings of Mattingly with that of Garth. Additionally, Garth in view of Mattingly does not disclose claimed elements such as the detachable chin strut. Accordingly, withdrawal of the 35 U.S.C. §103 rejections are respectfully requested.

#### Allowable Subject Matter

Applicants thank the Examiner for allowance of claims 10 and 16 when rewritten in independent form. Accordingly, claims 44 and 48 have been added.

New claim 44 encompasses limitations of claim 10 and includes all limitations of the base claim and any intervening claims (namely, claims 1, 7 and 9). It is noted that one element in this combination was added as dependent claim 46. The element is the straps for securing the back to the anterior plate assembly. Based on the Examiner's reasons for allowance it was determined that this element could be a dependent claim.

New claim 48 encompasses limitations of claim 16 and includes all limitations of the base claim and any intervening claims (namely, claims 1 and 28).

Prior Art

Applicants note the prior art made of record and not relied upon.

Conclusion

Applicants believe that all pending claims are allowable over the cited prior art and respectfully request early and favorable notification to that effect.

Respectfully submitted,  
SCHNADER HARRISON SEGAL & LEWIS LLP

Dated: \_\_\_\_\_

By: \_\_\_\_\_

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